

Appl. No. : 09/574,819
Filed : May 19, 2000

REMARKS

Applicant wishes to thank Examiner Romeo for the courtesy extended to Nancy Vensko, attorney of record, on December 8, 2004. The Interview Summary Form PTOL-413 summarizes the discussion held at the personal interview. The present response to the outstanding Office Action includes the substance of the Examiner Interview.

A. Compliance with 35 USC 102

The Patent Office rejected Claim 27 under 35 USC 102(a) as being anticipated by Storm et al., Nature 368:639 (14 April 1994), which describes a sequence encoding a protein comprising SEQ ID NO:24 but does not describe chondrogenic activity. According to MPEP 715, a Declaration under 37 CFR 1.131 can be used to overcome a 35 USC 102(a) rejection. Applicant filed a Declaration of Prior Invention in the United States To Overcome Cited Publication Under 37 CFR § 1.131, to swear behind Storm et al. at a date prior to 14 April 1994. The Patent Office questioned its effectiveness to overcome the Storm reference. As described below, the declaration is effective to overcome the Storm reference.

B. Compliance with 35 USC 103

The Patent Office rejected the claims under 35 USC 103(a) as being unpatentable over Storm et al., Nature 368:639 (14 April 1994), and Neidhardt PCTEP93/00350, published 19 August 1993. Under the statute, a patent may not be obtained if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made. Neidhardt is admitted not to describe a sequence encoding a protein comprising SEQ ID NO:24, only expression vectors, host cells, and processes for the production of proteins. The Rule 131 Declaration establishes prior invention prior to 14 April 1994. At the time the invention was made, Neidhardt's description of only expression vectors, host cells, and processes for the production of proteins could not have rendered the subject matter as a whole obvious because a sequence encoding a protein comprising SEQ ID NO:24 was unknown. The secondary reference does not fill in the gap left by the antedating of the primary reference, thus the rejection cannot prevail.

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C. Generic Applicability of the Rule 131 Declaration

The Patent Office questioned the effectiveness of the Rule 131 Declaration to overcome the Storm reference. As the Patent Office has acknowledged, the declaration evinces evidence of the possession of a species (bovine CDMP-2) of the claimed genus of SEQ ID NO:24, to swear behind the species (mouse GDF-6, aka CDMP-2) of the Storm reference. The issue is whether prior completion of one species put the Applicant in possession of the claimed genus of CDMP-2s. According to MPEP 715.03 "Genus Claim," the test is whether the species provided an adequate basis for inferring that the invention has generic applicability. As detailed in the Rule 131 Declaration, e.g., ¶ 6, and Exh. B, Applicant had possession of not only one species (CDMP-2) but also two species (CDMP-1) that are members of the class of CDMPs having a common SHLEP motif in SEQ ID NO:24. The inventors identified two novel members of the BMP family, CDMP-1 and CDMP-2, which are members of the TGF- β superfamily. This superfamily was known at the time to include structurally related proteins that have biologically active carboxyl terminal domains. An alignment of the CDMP-1 and CDMP-2 carboxyl terminal domains indicates to one skilled in the art the highly conserved (and therefore functionally relevant) amino acids. The similarity between the two domains predicts the structural and functional significance of the common region. Therefore, while CDMP-1 contains a sequence that falls outside the sub-class of CDMP-2, both species are members of a common CDMP class. In parallel, one with ordinary skill in the art would expect that bovine CDMP-2 would be a species that would be accompanied by another co-species (such as human CDMP-2 or xenopus CDMP-2 or zebrafish CDMP-2) to form the class of CDMP-2s, just as CDMP-1 is accompanied by another co-species CDMP-2 to assemble into the class of CDMPs. Based on the possession of two species CDMP-1 and CDMP-2 defining the class of CDMPs and the principle that bovine CDMP-2 anticipates a genus of CDMP-2s that includes other members, like human CDMP-2 and xenopus CDMP-2 and zebrafish CDMP-2, the conclusion is that the evidence provides an ample basis for inferring that the invention has generic applicability.

D. Implied Additional Structure in the Claims

The Office has rejected Claims 27-32 under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Office has indicated that the species

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described with particularity are not representative of the genera implied by the minimal structural limitations imposed by the claims, and that the skilled artisan would thus not have recognized that the inventors were in possession of the invention now claimed at the time the application was filed. The rule is that the specification must describe the invention throughout its scope. Here, Claim 27 provides both structural and functional limitations sufficient to convey to one skilled in the art that the inventors were in possession of the claimed invention. Structure is defined by the requirement that the protein comprise a sequence having the SHLEP motif of SEQ ID NO:24. Function is defined by the requirement that the protein have "chondrogenic activity *in vivo*", which is supported by the reported species. Furthermore, additional structure is implied by the requirement that the protein be a member of the TGF- β family. The TGF- β family is a well characterized family of proteins with common structural and functional properties, as indicated by the sections of the specification referenced by the Examiner. Consequently, the claimed protein will be a bioactive protein likely characterized by 7 highly conserved cysteine residues characteristic of the TGF- β family, amino acid sequence identity of at least about 50% with other members of the BMP family, and equivalence in terms of full-length sufficient to function as the C-terminal domain of 120 amino acids containing the seven highly conserved cysteines characteristic of the TGF- β family. Because of the implied additional structure in the claims, the conclusion is that the claims are in compliance with 35 USC 112, first paragraph.

E. Double Patenting Issue

The Patent Office provisionally rejected Claim 27 on the grounds of obviousness-type double patenting over claims 10 and 11 of copending Application No. 10/379,830. According to MPEP 804 (I) (B), if the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the Examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent." Here, the present application is otherwise in full compliance with the Patent Statute and the "provisional" double patenting rejection in it is the only rejection remaining in the present application. Thus, the MPEP urges the Examiner accordingly to withdraw that rejection and permit the present application to issue as a patent.

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CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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Dated: 2/28/05

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